APR 2 5 2002

K013517

510(k) Summary of Substantial Equivalence

Date Prepared: October 19, 2001

Submitter:
Medtronic, Inc.
7000 Central Ave. N.E.
Minneapolis, MN 55432

Contact:
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Product Regulation Manager
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Trade / Proprietary Name: Medtronic Model 10600 Deflectable Catheter System

Common Name: Catheter, Percutaneous

Device Classification: Class II, 21 CFR 870.1250

Product Code: 74 DQY

Device Description

The Medtronic Model 10600 Deflectable Catheter System features a percutaneous needle and syringe to access the venous insertion site, a guide wire to access the vein, an adjustable hemostasis valve to reduce blood loss during the implant procedure, a deflectable catheter to introduce a transvenous device, a deflectable catheter dilator to facilitate deflectable catheter passage, and slitters to remove the deflectable catheter.

The Model 10600 Deflectable Catheter System is provided STERILE and is intended for single use only.

The Model 10600 Deflectable Catheter System combines devices that are either cleared for market distribution via 510(k) or are exempt from Premarket notification because of Class I designation.

Indications for Use

The Medtronic Model 10600 Deflectable Catheter System is indicated to provide a pathway through which diagnostic and therapeutic devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Substantially Equivalent Devices

Medtronic Model 10600 Deflectable Catheter System Predicate Devices

Medtronic Model 10600 Deflectable Catheter System	Predicate Device	Predicate Device Manufacturer	510(k)
Guide Catheter	Model 6216 Medtronic Attain LDS Left-heart delivery system	Medtronic, Inc. Minneapolis, MN 55432	K012130
	Model 6218 Medtronic Attain Access Left-heart delivery system	Medtronic, Inc. Minneapolis, MN 55432	K012083
	GCIII (Vector, Vector X) Coronary Guiding Catheter	Medtronic Interventional Vascular (MIV) Danvers, MA 01923	K950179
	Cardima Naviport Deflectable Guiding Catheter	Cardima Fremont, CA 94538	K974683
	SafeSheath CSG (Same as SafeSheath MSP)	Thomas Medical Malvern, PA 19355	K003731
	Marinr Series EP Diagnostic Catheters	Medtronic CardioRhythm Minneapolis, MN 55432	K931794
Guide Catheter Dilator **Adjustable Hemostasis Valve** **Guide Wire** **Guide Catheter Slitters** **Guide Catheter Percutaneous Introducer Components**	Model 6216 Medtronic Attain LDS Left-heart delivery system	Medtronic, Inc. Minneapolis, MN 55432	K012130
	Model 6218 Medtronic Attain Access Left-heart delivery system	Medtronic, Inc. Minneapolis, MN 55432	K012083

Additionally, the sterilization process and biocompatibility of the Medtronic 10600 Deflectable Catheter System is substantially equivalent to the following devices:

MedAmicus, Inc. Percutaneous Introducer (also known as Solotrak)	MedAmicus, Inc. Plymouth, MN 55447	K893658
MedAmicus, Inc. Percutaneous Venous Introducer	MedAmicus, Inc. Plymouth, MN 55447	K965167
Medtronic Attain LDS Model 6216 Left-heart delivery system	Medtronic, Inc. Minneapolis, MN 55432	K012130
Medtronic Attain Access Model 6218 Left-heart delivery system	Medtronic, Inc. Minneapolis, MN 55432	K012083

Summary of Studies

Device integrity testing was conducted to support that the Medtronic Model 10600 Deflectable Catheter System is equivalent to the predicate devices. Testing included: Environmental Conditioning, Mechanical Testing, Compatibility Testing, Package/Shelf Life Testing. All device test results for the Medtronic Model 10600 Deflectable Catheter System met specified requirements.

Biocompatibility Information

Biocompatibility testing was conducted on all blood contacting materials. The testing performed on this product was done in accordance with ISO 10993-1 and results demonstrate that all materials were found to be biocompatible.

Sterilization Validation

The Medtronic Model 10600 Deflectable Catheter System is sterilized using a validated 100% Ethylene Oxide (EtO) sterilization process.

Conclusion

Through the data and information presented, numerous similarities support a determination of substantial equivalence and therefore market clearance of the Medtronic Model 10600 Deflectable Catheter System through this 510(k) Pre-market Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2002

Ms. Kristy K. Mollner, RAC
Product Regulation Manager
Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K013517
Trade Name: Model 10600 Deflectable Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY
Dated: February 1, 2002
Received: February 4, 2002

Dear Ms. Mollner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

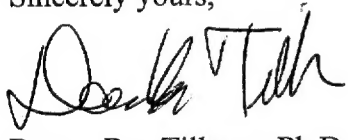
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): N/A K013517

Device Name: Model 10600 Deflectable Catheter System

Indications For Use: The deflectable catheter system is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013517